DEPARTMENT OF HEALTH AND HUMAN SERVICES

5063

RB 1/18/01

Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

January 16, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2001-011

James A. Brown, President
Fourth & Pomeroy Associates, Inc.
P.O. Box 516
Clay Center, KS 67432

Dear Mr. Brown:

Recently an inspection was made of your medicated feed mill operation located at 4th & Pomeroy, Clay Center, Kansas. This inspection was conducted on November 28, 2000, by an inspector with the Kansas Department of Agriculture, who documented significant deviations from Current Good Manufacturing Practice (CGMP) Regulations for Medicated Feeds (21 CFR, Part 225). Such deviations cause the medicated feeds manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Observations include failure to assure that all medicated articles used in production of medicated feeds are within the their expiration date; failure to assay medicated feeds as required; failure to assure that medicated feed labels are accurate and complete.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. A copy of the Form FDA 483 is enclosed for your information.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License, under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). (This letter constitutes official notification under the law.) Based on the results of the November 28 inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new

animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District

Enclosure - Form FDA 483